UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,723	03/24/2006	Richard George Leonard Morgan	HO-P03185US0	6853

26271 7590 12/19/2007

FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,723	MORGAN ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 16-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,16,18 and 19* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-9, 16-19 remain pending. Applicants elections are acknowledged:

- the disorder to be treated in the elected method is cancer;
- the peptide to be used in the elected method is WYPWMKKHHR
- the route of administration in the elected method is i.v. injection
- in the elected method, the aberrant cell division is occurring in prostate cancer cells.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 16, 18, 19 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to each of the following: (a) a method of treating disorders in which cell division is too high, and (b) a method of treating disorders in which cell division is too low. However, applicants are not enabled for both of these. For

example, if proliferation of T cells in an immunocompromised person is insufficient, administration of one of the disclosed peptides would likely exacerbate his or her condition. Given that the peptides will exacerbate various disease conditions, one cannot "predict" therapeutic efficacy.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Accordingly, "undue experimentation" would be required to treat diseases in which cell division is already too low.

Claims 4, 5, 7, 9, 16, 19 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In each of claims 4, 5, and 7, asparagine and/or glutamine are described as amino acids which bear a charged side chain. Applicants are requested to explain the reason for such a characterization.

- In claims 9 and 16, the relevant "SEQ ID NO:" should be recited.

- In claim 19, the phrase "said cells" lacks antecedent basis (notwithstanding the presence of the phrase "cell division" in claim 1).

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Lillie (US 2003/0124128).

Lillie discloses (paragraph 271, page 27) that one of the peptides of table 1 can be used as a vaccine for the treatment of breast cancer. In table 1, one finds SEQ ID NO: 214. Beginning at residue number 96, the sequence of this peptide is as follows:

-Phe-Pro-Trp-Met-Lys-Glu-Lys-Lys-Ser-

Thus, this peptide falls within the scope of claim 1.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Lorens (US 2004/0053233)

Lorens discloses (e.g., paragraph 0168) that the peptide of SEQ ID 121 is effective to modulate angiogenesis. Beginning at residue 95, the subsequence is as follows:

Phe-Pro-Trp-Met-Lys-Glu-Lys-Lys-Ser

This peptide, of course, falls within the scope of instant claim 1.

As applicants are likely aware, there are a considerable number of oncologists who subscribe to the belief that compounds which inhibit angiogenesis will be effective to inhibit tumor growth.

Thus, the claim is rendered obvious.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Rubenfield (USP 6,551,795).

Rubenfield discloses various peptides and proteins. Also disclosed (col 37, line 41+) is that an immunogenic fragment of *P. aeruginosa* can be used as a vaccine against the bacteria.

Among the sequences which fall within the scope of instant claim 1 is SEQ ID NO: 32984. Beginning at residue 28, the following subsequence is present:

Trp-Asp-Trp-Met-Ser-Arg-Arg-Arg-Arg-Leu-Ser

This falls within the scope of instant claim 1, given that any amino acid can be present between the methionine residue and the amino acid designated as X4. Thus, the "disorder in which aberrant cell division occurs" is a bacterial infection. The cell division may not be "aberrant" from the perspective of the bacteria, but from the perspective of the infected human who would much prefer to be healthy, the cell division is indeed aberrant.

Thus, the claim is rendered obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER